

# Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: a feasibility trial with an embedded qualitative component

<b>Submission date</b> 04/09/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/09/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/07/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In the UK 3.2 million working days are lost annually due to 30% of adults experiencing low back pain at any one time. 20% of individuals with low back pain seek care from their GP, representing 7% of all GP consultations. Early assessment and management of low back pain is important to reduce long-term pain and disability. Currently, there are too few GPs to meet the demands of the British public, with numbers predicted to fall further by 2020. To help combat this shortage, a range of organisations including the British Medical Association and the Chartered Society of Physiotherapy have committed to enabling direct access to physiotherapists in their local health centre without having to see a GP first for problems such as low back pain. It is envisaged that Advanced Physiotherapy Practitioners (APPs) working in these roles will prescribe medicines such as painkillers as part of a holistic treatment strategy to get patients managing their back pain as quickly and as best as possible. Physiotherapist prescribing remains novel, with the first prescribers qualifying in 2013. The true benefits now need to be evaluated, to do this we need to complete a clinical trial. To ensure that we are able to complete a trial of worth, we are first completing a feasibility trial.

### Who can participate?

Patients aged 18 and over with low back pain

### What does the study involve?

As per current normal practice, an APP completes the initial assessment and physiotherapeutic treatment of participants as deemed appropriate (traditional role). In addition to the physiotherapist's traditional role, the APP can prescribe medicines independently. If advice about medication or prescription drugs are required/no longer required, these are prescribed /de-prescribed by the APP immediately, rather than referring the patient back to their GP for assessment for medications as per current normal practice. The medications provided should be taken by the patient as prescribed in the time frames discussed in the clinical consultation. Following initial assessment by a physiotherapist the participants are required to complete

online questionnaires at 6 and 12 weeks. The trial explores the measures used to assess outcomes from treatment by using questionnaires and small devices call accelerometers (like 'fitbits') which assess how active or still people are during the day. The trial also explores how patients and physiotherapists involved found taking part via focus groups and interviews.

What are the possible benefits and risks of participating?

It is anticipated that the results of this trial will be used to help design a full trial. The information participants provide may help them and other patients in the future. It will not change the treatment that they receive for their back pain. There are no anticipated risks associated with undertaking this study and the only cost to the participant(s) is the time involved with completing the questionnaire and (for some people) attending a focus group. Participation in this study is entirely voluntary. It is possible that when talking about a participants back pain or filling in the questionnaire participants may be asked to relive events which are emotional for them. However, every effort will be made to ensure that participants are comfortable at all times.

Where is the study run from?

1. Guys and St Thomas' NHS Foundation Trust (UK)
2. Windermere Health Centre & Ambleside Health Centre (UK)
3. Sheffield Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

May 2018 to December 2019

Who is funding the study?

1. Health Education England (UK)
2. Private Physiotherapy Education Fund (UK)

Who is the main contact?

Mr Timothy Noblet

## Contact information

**Type(s)**

Public

**Contact name**

Mr Timothy Noblet

**Contact details**

Centre of Precision Rehabilitation Spinal Pain  
School of Sport, exercise and Rehabilitation Sciences  
University of Birmingham  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TT

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

250734

**ClinicalTrials.gov number****Secondary identifying numbers**

RG\_18-101, IRAS 250734

## **Study information**

**Scientific Title**

Independent prescribing by advanced physiotherapists for patients with low back pain in primary care: a feasibility trial with an embedded qualitative component

**Study objectives**

Aim: To evaluate the feasibility, suitability and acceptability of assessing the effectiveness of independent prescribing by advanced physiotherapy practitioners (APPs) for patients with LBP in primary care, to inform the design of a future definitive stepped-wedged cluster trial.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 30/10/2018, London - West London & GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; 0207 104 8124; NRESCommittee.London-WestLondon@nhs.net), ref: 18/LO/1793

**Study design**

The feasibility trial will utilise a mixed-methods research approach, comprising of:

1. A quantitative one-armed feasibility trial
2. Qualitative semi-structured interviews and patient focus groups, using thematic analysis

**Primary study design**

Interventional

**Secondary study design**

Feasibility trial with an embedded qualitative component

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

**Health condition(s) or problem(s) studied**

## Low back pain

### Interventions

Randomisation will not occur in this feasibility trial as the aim is to test the methods etc. The feasibility trial will use the proposed experimental arm for the full study to test the feasibility of the methods, outcome measures, analysis and synthesis. The control arm of the definitive trial will be current normal practice. As per current normal practice, an APP acting as a FCP will complete the initial assessment and physiotherapeutic treatment of participants as deemed appropriate through evidence based clinical reasoning and best practice (traditional role). In addition to the physiotherapist's traditional role, the APP will have the competence and legal ability to prescribe medicines independently. If advice about medication or prescription drugs are required/no longer required within the multi-modal physiotherapeutic context, these will be prescribed/de-prescribed by the APP immediately, rather than referring the patient back to their GP for assessment for medications as per current normal practice. The medications provided should be taken by the patient as prescribed in the time frames discussed in the clinical consultation. Following initial assessment by a physiotherapist the participants will be required to complete online outcome measurement questionnaires at 6 and 12 weeks.

### Intervention Type

Mixed

### Primary outcome measure

Measured at 6 and 12 weeks:

1. Overall pain, measured using the Numerical Rating Scale (NRS)
2. Disability, assessed using the Roland Morris Disability Questionnaire (RMDQ)

### Secondary outcome measures

Measured at 6 and 12 weeks:

1. Health-related quality of life, measured using EQ5D
2. Kinesiophobia, measured using the Tampa scale
3. Physical activity/sedentary behaviour, measured using accelerometers
4. Sleep, measured using accelerometers
5. Return to work (days)
6. Prescription utilisation (number of occasions)
7. Number of appointments with other healthcare professionals about this episode of LBP

### Overall study start date

01/05/2018

### Completion date

31/12/2019

## Eligibility

### Key inclusion criteria

1. Male and female patients, aged >18 years
2. Non-specific LBP +/- leg pain requiring medication advice and drug prescription on assessment
3. Classified as Moderate risk using the STarT Back Tool (classified as potentially benefiting from medicines and active physiotherapy treatment)

4. Able to read/communicate in English (due to funding restrictions for interpreters and translators limited in the inclusion of participant speaking other languages)
5. Capable of following the demands inherent of the study

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

30

**Total final enrolment**

29

**Key exclusion criteria**

1. Signs of lumbar nerve root compression
2. Red Flags including potential spinal fracture, inflammatory disease, infection or malignancy
3. Spinal stenosis
4. Suspicion of or confirmed corda equine syndrome
5. Does not have capacity to consent

**Date of first enrolment**

01/10/2018

**Date of final enrolment**

10/04/2019

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Guys and St Thomas' NHS Foundation Trust

London

United Kingdom

SE1 9RT

**Study participating centre**  
**Windermere Health Centre & Ambleside Health Centre**  
Cumbria  
United Kingdom  
LA23 2EG

**Study participating centre**  
**Sheffield Teaching Hospitals NHS Foundation Trust**  
Sheffield  
United Kingdom  
S5 7AT

## **Sponsor information**

**Organisation**  
University of Birmingham

**Sponsor details**  
Edgbaston Park Road  
Birmingham  
England  
United Kingdom  
B15 3TT

**Sponsor type**  
University/education

**ROR**  
<https://ror.org/03angcq70>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Health Education England

**Funder Name**

## Results and Publications

### Publication and dissemination plan

The dissemination strategy is multi-faceted in order to achieve maximum awareness and impact, and therefore potential change to NHS perceptions, current management strategies and service delivery in the longer term.

#### Professional dissemination:

1. A study report will be submitted to the funders and ethics committees
2. The Investigators will rapidly disseminate (oral presentation, email, social media) key findings to their clinical colleagues in the NHS and HEE in preparation for a full cRCT
3. The findings will be presented in an article that will be submitted to a high impact open access journal, accessible to UK and international professionals, targeting Plos One
4. Findings will be presented at Physiotherapy UK, and WCPT to target physiotherapists nationally and internationally

#### Patient/user dissemination:

1. A lay summary of the report will be written for patients
2. All study participants will receive a copy of the lay summary of findings
3. The source of funding will be acknowledged in all dissemination. Dissemination of findings will ensure confidentiality to participants

### Intention to publish date

01/01/2020

### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

### IPD sharing plan summary

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	01/05/2019	11/05/2020	Yes	No
<a href="#">Results article</a>	results	17/03/2020	21/07/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No